Physician-Patient Cost Conversations in Rheumatoid Arthritis:
The Patient Experience at the Intersection of High Cost and Health Policy

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A thesis submitted to the department of Public Policy Studies for honors.
Duke University
Durham, North Carolina
2016
Abstract

The out-of-pocket cost burden associated with healthcare in the United States imposes broad hardship on patients. One quarter of Americans struggle to pay their healthcare bills, and over half of personal bankruptcy filings in the United States cite healthcare expenses as a contributing factor. This study examined 268 transcripts of audio-recorded clinic encounters between rheumatoid arthritis patients and their rheumatologists to better understand the patient experience in the face of high cost and begin to inform high-impact areas for policy solutions moving forward. Qualitative analysis of the transcripts identified three themes – emotional response, difficulty managing complexity, and cost-induced non-adherence – that characterize the patient experience when dealing with high cost. Informed by these transcript findings, subject matter expert interviews directed the policy recommendations. In the future, policymakers should continue to leverage the patient experience to motivate policy changes that reduce the cost burden associated with expensive medical care.
Acknowledgments

I would like to thank my advisor, Dr. Peter Ubel, and his team, J. Kelly Davis and Christine Kirby, for their help and advice throughout this process.

I would also like to thank Dr. Christina Gibson-Davis and the thesis program at large, including my classmates and Dr. Pamela Edwards, my Duke Reader, for providing fresh eyes and feedback as the project came together.

I also appreciate the constant support of my friends over the course of this past year.

Finally, thank you to my parents for providing feedback and encouragement on this project, and more generally for giving me the opportunity to be here.
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**DR:** And copay is going to be increased too?

**PT:** Um, I think so. It's pretty much everything, I have to pay everything until I reach the deductible and then for the medications, for the specialty med…it went from $80 coinsurance per month…to, I'm sorry $80 copay for my [Enbrel]…to 50% coinsurance.

**DR:** So 50% coinsurance, so whatever it cost for the drug, you have to pay 50%, and we're looking at Enbrel, which is quite expensive. Are you going to be able to handle that?

**PT:** At this point, I don't know. I'm – I'm a little afraid.¹

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*As the above exchange illustrates, paying for healthcare in the United States has become a critical issue.*

¹ **PT:** Patient; **DR:** Doctor
Introduction

Over the past century, paying for healthcare in the United States has transitioned from a system in which patients deal exclusively with doctors to one in which they use health insurance to pay for their care and insulate themselves from potentially high costs. Under this system, the majority of Americans pay monthly premiums to an insurer – either public or private – and in return the insurer pays for a majority of the costs of care. In recent years, however, payers have increased the use of cost-sharing mechanisms to make patients more price sensitive about their healthcare decisions, relieve payer liabilities for costs of care, and introduce market forces into healthcare (Ubel 2014). These post-insurance costs of healthcare (i.e., what the patient pays in addition to monthly premiums) are generally divided into three categories: copayment, coinsurance and deductible.² Payers often use copayments for lower-cost treatments, procedures and office visits where little variability in price exists. Coinsurances generally apply for services with greater variability in price because they make the patient more sensitive to price differences. These forms of out-of-pocket (OOP) cost sharing are used to shift costs from payer to patient and deter patients from over utilizing high cost services.

As a result of increased cost sharing for healthcare services, American patients face a significant OOP cost burden. In 2012, more than one in four American families reported struggling to pay for the costs of their healthcare (Cohen and Kirzinger 2014), and in 2013 the American Medical Association found that patients were liable for roughly 25% of their medical bills (Dolan 2014). For perspective, a common condition

² **Copayment**: A fixed price patients pay each time a particular medical service is received. **Coinsurance**: The percentage of the bill for which a patient is responsible. **Deductible**: The amount a patient owes for covered services in a given year before the health plan begins to pay.
like diabetes can cost as much as $4,000 in annual OOP costs if uncomplicated, or as much as $40,000 if the patient experiences problems during the year (Ubel 2014). Medical care is expensive, and even insured patients are not insulated completely from its costs.

The present study focuses on Rheumatoid Arthritis (RA) as a case study for exploring the greater issue of OOP cost burden in America. RA is a chronic disease that manifests with joint inflammation, and when untreated, leads to extreme discomfort, disfigurement and disability. Unlike osteoarthritis, RA is an autoimmune disease that affects the joint linings, generally in the hands and feet, and causes painful swelling. Even though RA only affects a small percentage of the population, it presents a significant decrease in quality of life for those it afflicts. Slowing the progression of the disease is the main goal in treating RA.

Because specialty drugs – high-priced medicines that often require special handling, administration, and approval from the insurance company – are one of the main treatment options for RA patients, understanding the specialty pharmacy space is crucial to this project. Specialty medication is one of the fastest-growing areas of medical spending; although specialty drugs account for only 1% of prescriptions, they represent 20% of American drug spending (Gebhart 2012). Furthermore, spending on these medications is expected to climb to 44% of total drug spend by 2030 (Kim, Rascati et al. 2011). In 2008, the average annual specialty drug expenditure was $11,746 in 2010.
dollars (Romley, Sanchez et al. 2012). Due to the above-mentioned cost-sharing mechanisms, namely coinsurance, specialty drug patients – the category into which many RA patients fall – are at an elevated risk for high out-of-pocket spending compared to their peers (Goldman, Joyce et al. 2006). Although rheumatoid arthritis is the specific focus of this study, understanding the cost issues associated with RA treatment will also give insight into the broader use of specialty drugs. Furthermore, the results and observations drawn below are transferable to many chronic illnesses faced by Americans.

Through examining in-clinic transcripts of cost conversations between Rheumatologists and their patients, this study makes two main contributions to the literature. First, it describes in depth what happens in clinics when patients have OOP cost problems, including what those problems look like and how doctors successfully or unsuccessfully try to mitigate them. Second, it explores health policies that respond to the high patient OOP cost burden. Because unresolved and excessive cost burden harms patients, the study concludes by discussing possible policy solutions to help alleviate future patient burden.

**Main Questions**

In rheumatology clinic encounters, how often do patients and physicians discuss issues of high cost?

What elements of the patient experience emerge during clinical interactions about high cost?

What are potential policy solutions to help relieve high cost for RA patients?

**Background**

**Overall Medical Spending in the United States**
Although the rate of growth in healthcare spending is starting to slow, the United States still pumps enormous amounts of money into the healthcare system each year. In 2011, national health spending approached $2.7 trillion dollars, representing almost eighteen percent of the country’s Gross Domestic Product (GDP). By comparison, France (11.7%), Denmark (10.6%) the United Kingdom (9.1%) all spend significantly less as a share of GDP (The World Bank 2015). What is more, total US spending is projected to climb to almost $5 trillion by 2021. Roughly half of the projected US spending growth will be financed by the government, and the other half by the private sector (Center for Medicare and Medicaid Services 2011). In addition to the high absolute spending on healthcare, the United States ranks at the top of the list for per capita healthcare dollars. Overall, the United States averaged $7,097 per person in annual healthcare spending in 2010, and that number increases to $18,424 for people over the age of sixty-five (Lassman, Hartman et al. 2014).

Prescription drugs represent a significant portion of total health spending. Between 2007 and 2010, almost one half of Americans reported taking at least one prescription drug, and ten percent reported taking at least five drugs simultaneously. These patterns contributed to the $263 billion spent on prescription drugs in 2011, just under 10% of total health spending (National Center for Health Statistics 2014). Furthermore, prescription drug spending continues to grow; the rate of spending growth increased 2.9% from 2010 to 2011 – up from 0.4% in 2010, but down from 7.8% between 2000-2010 – in part because of the increasing prices of brand name and specialty drugs (Hartman, Martin et al. 2013).
Because of this spending dilemma, payers are increasingly pushing the costs of care onto patients. Although patient OOP spending represents 15% of personal healthcare spending – down from more than 50% in 1965 – the significant rise in overall spending means that patient liabilities have actually increased in real terms, and they still pose a significant burden for patients (Baicker and Goldman 2011). Both the decrease in cost sharing as a percentage of total personal health spending and the increase in real personal spending have been linear trends since 1965 (Baicker and Goldman 2011).

The Effects of OOP Cost Burden in the United States

The effects of OOP costs broadly impact patients’ lives. First, excessive costs can stand in the way of patients receiving the most effective treatments. If cost sharing is too high, patients might postpone or entirely abandon a prescribed drug regimen, or they may forgo physician visits to avoid OOP spending (Kim, Rascati et al. 2011, King and Mitchell 2012). Second, high OOP costs can inflict financial ruin on patients (Polinski, Mohr et al. 2009). One study found that medical debt is a contributing factor to roughly fifty-three to sixty-two percent of personal bankruptcy filings (Ramsey, Blough et al. 2013).

Given this context, “financial toxicity” is the result of a budding school of thought seeking to situate the financial side effects of care along side the clinical ones (Ubel, Abernethy et al. 2013). That is, in addition to the medical side effects of a drug or treatment, is there a risk for financial harm, and how big is it? When patients are saddled with high medical spending, they may suffer across many dimensions of their lives. For example, patients undergoing cancer care often have to make choices between paying for medical care and other basic life necessities (Zafar, Peppercorn et al. 2013). Even insured
patients, especially those who are underinsured, are forced to decide how much of their limited resources to spend on medications, physician visits and other related expenses, knowing full well that it may preclude spending on necessities like housing, food and education, as well as frivolities like recreation, incidentals, and any number of other goods and services (Zafar and Abernethy 2013). This financially toxic environment surrounding healthcare directly harms patients (Zafar and Abernethy 2013).

**Rationale for Cost Sharing**

Cost sharing, as a mechanism, is not new. The push toward moving more financial responsibility to the patient traces its roots to the RAND Health Insurance Experiment (HIE) conducted between 1971 and 1986. Specifically, the RAND HIE randomized families across varying levels of cost sharing and followed them to monitor healthcare utilization. The major finding indicated in the HIE was that increases in cost sharing decreased patient use of services; families exposed to higher cost sharing used fewer services on average, across all socioeconomic statuses (Newhouse 2004). More recent studies have confirmed this phenomenon as well (Alexander, Casalino et al. 2003, Newhouse 2004, Dolan 2014).

For most people, these changes in benefit design – and the resulting effects on healthcare utilization – had minimal effects on health outcomes. However, people who were poor and sick\(^3\) – therefore needing more medical care – did experience harm (Newhouse 2004). This finding suggests that people with chronic conditions can be at significant risk for medical and financial harm when cost sharing approaches high levels.

\(^3\) In addition to the findings of the HIE, this effect is observed in middle and upper class families that need expensive medical care.
While greater discretion in healthcare resulting from increased cost sharing has some benefits (e.g., not paying for expensive, unnecessary tests), the same financial incentives can prevent patients from seeking and receiving essential services. In other words, the price signals that decrease demand for unnecessary care can also steer patients away from essential services (Alexander, Casalino et al. 2003). In fact, this question was one of the motivations for, and points of contention with, the HIE: would increased cost sharing decrease utilization for “necessary” and “unnecessary” services similarly, or would it affect them differently? The results of the experiment showed that utilization fell across all types of care as cost sharing increased. Of course, different services, treatments and procedures have different price elasticities of demand – that is, changes in price will have varying changes in the quantity demanded – but in general an increase in the price of a treatment will decrease demand for both necessary and unnecessary services. Decreasing demand for elective services such as cosmetic surgery may not be of concern, but decreasing demand for non-elective services – e.g., kidney dialysis – is potentially troubling.

**Why focus on OOP cost burden in RA?**

Although RA affects relatively few people, it can be a crippling disease. Within two years after diagnosis, roughly 20% of RA patients are “work-disabled,” and after ten years 50% are unable to work at all (Curtis and Singh 2011). Recent data suggest that roughly one percent of the United States population is diagnosed with RA, and that number climbs to about 2% in the over-60 year old population (Beard, Sleath et al. 2010, Yazdany, Tonner et al. 2015). Nonetheless, RA onset can come at any age and can stay with a patient for life. Using a metric called Years Lived with Disability (YLDs), which
measures intensity and prevalence to compare burdens of disease, the RA contribution to American YLDs in 2010 was 403,100, up 28% from 1990 (Murray, Abraham et al. 2013).

Specialty drugs, especially biologic Disease-Modifying Antirheumatic Drugs (DMARDs), are particularly effective at mitigating the effects of RA. The Food and Drug Administration approved the first biologic agent – etanercept – in 1998, and since then various biologic DMARDs have been used to retard disease progression, prevent further joint damage and improve patient quality of life (Curtis and Singh 2011). Since they entered the market, the receipt of biologic DMARDs has significantly increased; between 1999 and 2006, the US experienced a twenty-three-percentage point increase in prescriptions of biologies for RA, from 3% to 26% of patients (Curtis and Singh 2011, Harrold, Peterson et al. 2012). In 2012, three of the top ten medications by sales were biologic DMARDs: adalimumab ($4.3 billion), etanercept ($4.0 billion), and infliximab ($3.7 billion) (Ioannidis, Karassa et al. 2013). Meanwhile, prescribing patterns for non-biologic RA medicines have remained relatively constant (Harrold, Peterson et al. 2012).

However, these more effective drugs can be much costlier than non-biologics (Polinski, Mohr et al. 2009). One study found that biologics can saddle patients with up to $19,016–$23,000 in annual OOP costs, compared with $6,164 for non-biologic DMARDs (DeMaria, Acelajado et al. 2014). The high cost sharing associated with these drugs is partly a result of the liberal use of coinsurance; in 2011, the average coinsurance for specialty drugs was 32%, which likely exceeds the flat copay charged for other covered medicines (King and Mitchell 2012).
The high out-of-pocket costs associated with specialty drugs can stand as a barrier to successful treatment of the disease. When cost sharing is exceptionally high, patients may either avoid starting a medication regimen or exhibit poor adherence once they have begun (Polinski, Mohr et al. 2009, King and Mitchell 2012). For example, about half the patients in each condition of one study – RA, oral cancer and multiple sclerosis – decided not to fill their specialty drug prescription at the pharmacy upon learning how much it cost (King and Mitchell 2012). Other times, patients exhibit poor treatment adherence once they have started the medication because the OOP costs are too burdensome (Polinski, Mohr et al. 2009). Poor adherence can include taking the medicine less often than prescribed, taking lower doses or stopping the medication altogether.

To help reduce cost, many patients taking biologics can qualify for copay assistance programs in which the drug companies help patients cover the costs of their medications. In 2014, 561 such programs helped patients afford over 700 distinct medications (Starner, Alexander et al. 2014). That being said, participating in copay assistance programs is not always straightforward. First, not all patients know about these programs or are willing to fill out the paperwork with the drug company to enroll. Second, some programs put time limits on eligibility, so patients may again struggle with paying for the drug when they run out of time.

Because Rheumatologists have different treatment options and programs to reduce patients’ financial liabilities, they may want to pay attention to the financial impact of prescribing patterns, through listening to patient concerns when they arise, with the end goal of finding the most effective, least-cost treatment regimen for each individual patient (Polinski, Mohr et al. 2009).
What do we know about patient-doctor cost communication, especially in RA?

Despite a strong push in medicine toward shared decision-making, a thin literature about cost discussions suggests that physicians and patients engage in such conversations in a minority of clinic visits. Surveys reveal that both patients and doctors believe cost of care discussions are important, but that these conversations are uncommon (Alexander, Casalino et al. 2003). In fact, surveyed physicians acknowledge the significant disparity between their belief in having such discussions and what they actually do in practice (Alexander, Casalino et al. 2003). Furthermore, socioeconomic status is a predictor of cost conversation frequency: lower income families ($20,000-$59,999) are more likely to discuss medication costs than higher income families (> $60,000) (Beard, Sleath et al. 2010).

That said, more recent evidence shows that cost conversations are more prevalent than surveys suggest (Beard, Sleath et al. 2010, Hunter, Zhang et al. 2015). This change likely has many causes, including the development of new measurement methodologies that overcome survey research biases, and an increased policy priority on patient centricity in the healthcare process. One study found that RA medication costs were discussed in roughly one third of the sample clinic visits (Beard, Sleath et al. 2010). A recent study by Dr. Peter A. Ubel and his team confirmed this finding, and showed that patients and physicians discussed the cost of care in 30% of clinic visits in their sample population of breast cancer, depression and rheumatoid arthritis patients. Of these cost conversations, 44% dealt with reducing patient OOP costs (Hunter, Zhang et al. 2015).

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4 Dr. Peter A. Ubel was my advisor. I worked with him and his team – J. Kelly Davis and Christine Kirby – to conduct the research for this thesis.
Cost conversations can play a critical role in identifying price- and preference-sensitive treatments. In its guidelines, the American College of Rheumatology suggests that doctors discuss with patients the costs of treatments when choosing which one to pursue (Beard, Sleath et al. 2010). When physicians bring up the subject of cost, it opens the door for patients to discuss their own financial concerns (Hunter and Ubel 2014). Because RA can be treated using a variety of methods (Harrold, Peterson et al. 2012) with varying effectiveness and varying costs, doctors should be able to switch patients between treatments to find the one that optimizes the relationship between clinical outcomes and financial burden.

**General Aim**

The general research aim of this study is twofold: (1) to demonstrate what financial toxicity looks like in the clinic setting for rheumatoid arthritis patients, including the identification of themes describing the patient experience, and (2) to explore salient policies which respond to these cost issues for RA patients.

**Methods and Data**

**Research Design**

This descriptive study used qualitative methods. I immersed myself in the clinic transcripts and conducted content analyses to identify themes about cost problems, including the challenges patients and rheumatologists face regarding care costs, how patients and physicians navigate those cost problems, and the patient experience surrounding high cost. To record these themes, I developed coding categories that identified the various cost issues found in the transcripts. This study did not test hypotheses; instead, I engaged with transcripts to answer my research question about how
these conversations reveal the context of cost problems for RA patients and doctors. After recording examples of different cost-problem triggers and discussions revealing the patient experience, I conducted policy analyses – informed by expert interviews – to understand what health policies contribute to or resolve these in-clinic problems.

The two phases of this study – transcript analysis and policy evaluation – were worked in tandem. Qualitative analysis of the RA transcripts identified the patterns and themes of problematic cost conversations. What does it look like when a patient faces high cost? How do they interact with their doctor around these issues? Why are patients facing cost problems in the first place? The policy analysis relied on findings from the transcripts and expert interviews to fit the pieces together and determine what broader health policies could be at play.

The data came from transcripts of audio-recorded clinic encounters and thus avoided some of the biases inherent in survey data, such as social desirability and research bias. Much previous research on cost conversations comes from survey responses (Alexander, Casalino et al. 2003, Shrank, Asch et al. 2006, Bestvina, Zullig et al. 2014); these transcripts, however, served as more reliable data to help shed light on the ways rheumatologists and RA patients discuss cost issues.

**Data Collection**

The transcript data for this study came from the Verilogue Point of Practice database. Verilogue is a pharmaceutical research company that randomly recruits board-certified, high-prescribing physicians from across the country, who focus on direct patient care, to record clinic encounters. Verilogue pays these doctors to participate in the program, and uses the recordings for market research. Dr. Ubel’s research team analyzed
1,755 of these transcripts, spanning three medical conditions: 677 breast oncology visits, 656 rheumatoid arthritis visits, and 422 psychiatry visits. Transcripts were selected from the 1,000 most recently dated encounters for each condition, which they screened for five different criteria\(^5\) to narrow down the sample to the most relevant encounters.

The present study focused only on the 656 transcribed clinic encounters between rheumatologists and rheumatoid arthritis patients dating between May 2010 and February 2014. Specifically, I conducted content analyses on the subset of those 656 RA transcripts with cost conversations \((n = 268)\) in order to quantify the number of cost conversations dealing with issues of high cost. This work is an important next step in the research because it acknowledges that not all conversations about treatment costs indicate a problem; those that do, however, shed light on the ways patients struggle with high OOP spending and the causes for those problems.

The long-term result of cost conversations was not considered for the purposes of this study because the transcripts only show one point in time. Instead, each transcript was evaluated based on what was said in that discreet interaction.

The qualitative data for the policy analysis phase came from policy research and expert interviews. Interviewees represented the following categories: health policy expert, clinician, pharmacist, and hospital/health system administrator. I accessed these individuals through existing relationships Dr. Ubel’s team and I have. Interviews referenced the overall findings (and specific transcript examples) about cost-problem triggers and patient experiences, with interviewees discussing the ways health policies

\(^5\) Exclusions were for visits conducted by primary care doctors, nurse practitioners or nurses; which occurred outside the United States; involved patients under age 18; visits concerning axial spondyloarthritis rather than RA; or transcripts with only physician dictation.
and business considerations play into the observed issues. These conversations with experts helped frame the results and discussion sections of the thesis, where I talk about the patient experience and what policies could reduce patient burden.

**Data Analysis**

**Coding the Transcripts**

Transcripts were coded using the qualitative data analysis (QDA) software package from NVivo. The query function and data visualization tools in the program helped represent the data in various ways as I examined the transcripts.

I first performed an initial pass through of all 268 RA transcripts with cost conversations. At this stage, I looked specifically for problem presentations in which patients or doctors brought up cost issues and justified their burden. From these I made a new subset of transcripts dealing explicitly with high cost (n = 155), to be analyzed for the study. This count of high cost transcripts answered my first research question.

Next, I conducted thematic analysis. In order to do this, I worked with Dr. Ubel’s team to iteratively develop a coding scheme that identified examples of problematic cost conversations. All transcripts were double coded by me and another member of the team. We met regularly to discuss coding discrepancies, including discussion of why they occurred and necessary revisions to reduce differences going forward. Thematic analysis allowed me to group text sections in the transcripts together by theme, thus making sense of the themes as they emerged across the body of cost conversations. This work addressed my second research question regarding the themes encapsulated in the patient experience with high cost.

**Policy Analysis and Subject Matter Expert Interviews**
After identifying salient themes regarding the patient experience, I brought examples to subject matter experts and conducted interviews about which health policies relate and how they contribute to the cost issues doctors and patients face in the clinical setting (Appendix A). Expert interviews served two purposes. First, they were an additional data source that provided perspective on the transcript data. Because the interviewees all work in the healthcare industry in jobs that relate to specialty pharmacy, care delivery and payment, and/or health system administration, they were able to confirm that the transcript findings mirrored their experiences in practice. Second, these subject matter experts provided context on where the specialty pharmacy industry is going, including commentary on likely future trends, regulations and business decisions and trends. This latter purpose also informed the policy recommendations.

Interview findings are included in the results and discussion sections, combined with transcript analysis and reviews of existing literature, to help inform the cost problems I observed in the clinic encounters. These interviews further helped me learn about how clinicians and administrators attempt to mitigate patient burden. I did not interview patients because the transcripts served to provide the patient voice.

Coding Scheme

The first step in coding these RA transcripts was identifying instances of high cost conversations (Table 1). Specifically, I looked for conversations where doctors, patients and caregivers discussed costs in such a way that either person expressed concern or uncertainty about the ability to pay for a given medical treatment. There also were conversations in which high costs were discussed but no concern or uncertainty was expressed.

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6 Dr. Michael DeCoske, Associate Chief Pharmacy Officer, Ambulatory Services, Duke University Hospital; Kyle Cavanaugh, Vice President, Administration, Duke University; Dr. Yousuf Zafar, Medical Oncologist, Duke Cancer Center; Rujul Desai, Vice President, Avalere Health
expressed. These non-high cost conversations were relevant in two ways. First, insofar as
they showed that not all cost conversations are problematic, they also showed the relative
frequency with which cost conversations are precipitated by issues of high cost as
opposed to non-high cost. Second, these conversations helped illuminate greater system
issues for the discussion section (i.e. even though a particular patient may have
comprehensive insurance, drug prices are still quite high and the health system needs to
address pricing).

The inclusion criteria for high-cost conversations developed over the course of an
iterative coding process. Some criteria were straightforward: if a patient mentioned
struggling to pay for care; expressed distress over past, present or future costs; a doctor
mentioned an expensive treatment whose costs would be largely transferred to the
patient; or costs stood as a barrier to care; the conversation was deemed high-cost.
However, some cases were less clear. Take, for example, the question of insurance
coverage. If a doctor said ‘We’re going to get you covered and then we’ll start your
medication,’ high patient cost is not an immediate issue. If, on the other hand, the doctor
asked how a patient was doing on a particular drug and the patient said, “I stopped taking
that a while ago – copay was too high,” cost clearly stands as a barrier to treatment. In
short, non-high cost conversations were those in which the patient’s treatment did not
involve high cost, or the patient was successfully insulated from those costs.

Once I identified high cost conversations, I explored the subcategories of High
Cost Inquiries (Table 2). These subcategories illustrated the different ways high cost
conversations presented themselves, and also began showed the underlying causes of OOP
cost burden. Additional levels of coding provided greater detail as cost triggers became
better defined. Thorough analysis provided insight into which health policies contributed to, and responded to, issues of high cost. As this became clear, I coded portions of conversations for future use in the results and conclusion sections.

Coding these transcripts was an ongoing process. I continuously refined codes as I went by seeing how new transcripts fit into the existing coding categories. When new concepts arose, I created new codes or revised the current ones to account for the new transcripts and ensure my codes captured the different phenomena. This was a process of group consensus and iteration; Dr. Ubel’s team and I met periodically – with frequent email communication – to provide feedback on the coding process and resolve discrepancies. When there was disagreement, we discussed the cost conversation and compared it to others I had already coded to see how it compared to the established precedent. We then revised codes accordingly.

Results

My analysis of these transcripts shows patients experiencing and having to navigate high cost in 23.6% (n = 155) of the original 656 RA clinic encounters. The following results expose the patient experience in the face of high cost and then highlight two salient cost-reducing strategies.

Patient Experience

The effects of burdensome prescription drug cost sharing are multiple and significant. In the greater framework of “financial toxicity,” these transcripts show the ripple effects of high cost throughout a patient’s life; thus, they confirm Dr. Zafar’s previous research showing patients emotionally struggling with the costs of care and making tradeoffs between healthcare and other needs.
Three main themes emerged that describe the ways patients respond to high cost: (1) emotional responses, including feelings of being overwhelmed, afraid and frustrated; (2) patient difficulties in the face of complex cost-reducing strategies; (3) patient inability to afford treatment, leading to cost-induced non-adherence.

**Emotional Response**

Dealing with high cost can evoke emotional reactions for patients, including frustration, sadness and fear. Oftentimes patients do not expect to see these high costs, believing that paying a monthly premium means everything will be covered: “Yea, sure there’s a deductible, but they don’t expect the costs are going to be as high as they are in many cases. And that can be shocking” (Personal Interview, Zafar). Regardless of a patient’s ability to anticipate the costs, they can be stressful.

Furthermore, problems of high cost are not isolated among the uninsured. Even those with insurance can struggle to cover treatment-related costs. Jane is a middle-aged female with prescriptions for Enbrel, methotrexate and prednisone to treat her rheumatoid arthritis. While discussing treatment options with her rheumatologist, the conversation turned to cost sharing: “I have to pay everything until I reach the deductible and then for the medications…. It went…from $80 copay per month…to 50% coinsurance.” Her doctor responded, “So 50% coinsurance, so whatever the cost for the drug, you have to pay 50%, and we’re looking at Enbrel, which is quite expensive. Are you going to be able to handle that?” She replied, “at this point, I don’t know. I’m a little afraid.” Given that Enbrel can cost $3,200 per month, Jane could have experienced a $1,520 increase in her

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7 I use pseudonyms throughout the results section.
monthly out-of-pocket costs, or 1,900%. Following this increase, she commented to her doctor that she was “afraid,” unsure if she would be able to stay on the medicine.

Financially toxic situations like these can necessitate “tradeoffs.” Clinical anecdotes and formal research show that patients are “in some cases spending less on groceries, and cutting out vacations, spending their retirement savings, all to help pay for [the costs of] treatment” (Personal Interview, Zafar 2015). Seeing those types of decisions on the horizon, or facing them immediately, can infuse a clinical encounter with emotion.

Difficulty in the Face of Complexity

The origins of these emotional responses are varied, but one example was patient difficulty in the face of complexity. Although significant cost problems exist, myriad solutions and strategies can help physicians and patients reduce those costs. That said, strategies for cost reduction are not always easy to implement, and the complexity can in and of itself stand as a barrier to care.

Sometimes issues of insurance coverage pose complex problems for patients. Wendy is an elderly Californian with seven prescription medications, including Enbrel. Because she is low-income, she qualifies for Medi-Cal, California’s Medicaid program. When asked if she thought they were going to insure her again, Wendy replied, “I have no idea.” The doctor went on to explain, “…It’s really frustrating because they don’t want to give you the Enbrel until they get a denial from the Medi-Cal program. So you need to go to them and say, you’re costing me my medicine, you know? If you’re not going to give me the Medi-Cal, then give me the denial.” In this case, part of the barrier to Wendy getting treatment is the complexity of the approval process from the insurance
foundation. She can get the medicine paid for by Medi-Cal, or by the foundation, but only if Medi-Cal denies her. And, in this case, Medi-Cal is dragging its feet. Thus, the complex interactions between different payers, and the bureaucracy within payer organizations, stand in the way of Wendy receiving her medicine.

Signing up for and receiving copay assistance can also be a confusing process for patients. Jill is an elderly woman who acts as her husband’s caregiver. Sitting in the clinic discussing a prescription for biologic DMARDs with their physician, the doctor says, “So these are the big guns we’re talking about, right? The Enbrel, the Remicade.” Jill responds, “Right. We thought about, you know, if he goes to something like that, we're going to have to have some kind of help. And so they gave us a website but I mean we're not smart enough…to do that and we need help.” For this couple, a clear path to cost-reduction exists – copay assistance – but the process of pursuing that option seems insurmountable. In reality it is not always a question of intelligence, but instead sometimes of lacking the resources to navigate the complex application processes that can be associated with copay assistance.

When cost reducing strategies are too complex, patients continue to struggle to reduce cost. Furthermore, situations like these can lead to cost-induced non-adherence.

Cost-Induced Non-Adherence

Non-adherence can lead to negative health outcomes, especially with chronic diseases like rheumatoid arthritis. Unfortunately, abandoning treatment regimens is one strategy patients use to avoid high cost. Sometimes patients forgo starting a medication because the costs are too high: When a rheumatologist asks one elderly woman if she is doing better since starting a new medication, she responds, “[No], I couldn’t afford it, it
was $700.” In another case, a young female patient is not feeling well “because…you know, I was denied with the health insurance to do the infusion. Not denied, it was just going to cost too much.” She and her doctor had identified a promising treatment regimen but again high cost again stood as a barrier to care.

Other times, cost interrupts a successful treatment:

**DR:** And, uh, how long have you been off the Enbrel now? Has it been quite, quite a while?
**PT:** Yeah, quite a while, um-hum.
**DR:** Um, and the insurance, the copay was too much? So you really feel, feel as though you've been doing, uh, significantly worse since you've been off the Enbrel?
**PT:** Um-hum.
**DR:** Are you taking the methotrexate?
**PT:** No, because the insurance don't cover that anymore either.

Like Wendy, this woman is unable to continue with an effective treatment because the cost burden is too high.

Furthermore, high cost is not always foreseeable; these cases in particular can lead to cost-induced non-adherence. One patient talks about how she “used to take Humira, and, um, stopped it about a year ago…[because my] insurance companies changed, and I couldn't afford it. It went from $35 for a quarter to $2000 for 1 month”.

The shock factor associated with expensive treatments is compounded when the high cost follows previous experience with manageable levels of cost. She is used to being able to afford her medication, and responding well to treatment. When all of a sudden the cost becomes prohibitive, she has to stop and loses the benefits. Situations like these can lead to patient distress and physical harm in the long term.

**Salient Cost Reducing Strategies**
Previous analysis of these transcripts by Dr. Ubel’s team shows a great deal about the ways physicians and patients communicate about costs. Across all three disease states – breast cancer, RA and depression – 30% of clinic visits include a cost conversation, slightly more than half of which were initiated by the physician. Furthermore, these cost conversations are generally short. The median length of clinic visits in the sample is just under ten minutes, and the median length of the cost conversation is 68 seconds (Hunter, Zhang et al. 2015). Of all cost conversations, 44% involved discussions of strategies to reduce patient-cost (Hunter, Zhang et al. 2015). A number of such strategies exist for reducing cost, falling broadly into two categories: care plan changes (27%) and changing the logistics of the intervention (55%)\(^8\). Among changes to clinical care, finding a lower cost treatment alternative was one of the most common options (20%). Among strategies for lowering patient cost without changing the intervention, copay assistance was one of the most common strategies (25%).

Because pursuing copay assistance and less expensive treatment options are two salient strategies for patients and physicians, policy solutions that address these areas have the potential to be quite impactful. Nonetheless, these two strategies are not perfect. This next section discusses some of the challenges physicians and patients face when pursuing lower cost medications and copay assistance to reduce patient OOP cost.

**Implications of Lower Cost Treatment Alternatives**

Switching treatment plans to include lower-cost medication can be a successful strategy for reducing cost. Because RA treatment has many different drugs at its disposal, some patients do equally well on different medications. Other times, however, a patient will respond better to one type of drug than another. For example, a patient may respond

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\(^8\) These percentages do not add to 100% because there is also a category with overlap of the two strategies.
much better to a biologic DMARD than a non-biologic, which presents an ethical question around relying on less effective, lower cost alternative medications as a cost-reducing strategy: should patients be expected to withstand physical harm in the name of cost reduction?

When less effective medications replace more powerful ones, patients can experience harm. Continuing with Wendy’s story, when her doctor asked her if she had missed any doses, she replied, “I did miss it…because I’m having a problem with…Medi-Cal. The lady at the desk told me that my worker was out of town…and would be for two weeks.” Wendy goes on to say that she has “no idea” if she will get her Medi-Cal coverage back. Her doctor begins to discuss putting her on “methotrexate,” a less powerful but cheaper drug, because it “might help tide things over while, if you miss any shots….” Wendy interjects, saying, “You know, with the Enbrel, everything perked back up again…it’s a miracle actually.” Here is a patient for whom access to an effective medication is blocked by exorbitant cost. Furthermore, her situation is compounded by knowing what benefit she derives from the Enbrel and by the uncertainty of her future insurance status. Although methotrexate would reduce her cost, she responds best to the Enbrel. In this case, relieving some financial harm could impose physical harm.

Copay Assistance

Despite the immense benefit to patients who receive copay assistance (Table 3), barriers exist when patients are on public insurance (Table 4). The Office of Inspector General (OIG) at the Department of Health and Human Services (HHS) issued a Special Advisory Bulletin (SAB) in 2005, with an update in 2014, warning drug manufacturers that providing copay assistance directly to patients within Federal healthcare programs
could violate antikickback statutes because it provides a “remuneration” that encourages patients to use their particular drug. This restriction applies to physician-administered drugs covered under the Medicare Part B medical benefit and ones covered under the Part D prescription drug benefit (Howard 2014).

To avoid these strict regulations, manufacturers often use independent charities to make an end-run around antikickback laws. These charities act as buffers between the manufacturer and the patient to help ensure that money is not used to coerce treatment uptake (Office of Inspector General 2014). Many foundations will either focus on a wide array of diseases, or on one particular disease, provided it is not defined so narrowly that the donations effectively subsidize a specific product: “…an Independent Charity PAP must not function as a conduit for payments or other benefits from the pharmaceutical manufacturer to patients and must not impermissibly influence beneficiaries’ drug choices” (Office of Inspector General 2014). Despite the benefits to Federal health insurance programs resulting from these copay assistance regulations, they impose direct harm on patients.

Because the foundations, by definition, operate independently from the manufacturers, patients are forced to jump through yet another hoop to get the copay assistance they need. For elderly patients (e.g. a Medicare beneficiary), or patients with low health literacy (e.g. a low-income patient on Medicaid), this additional step can be problematic.

Another challenge for patients receiving copay assistance through third-party charities is that the assistance is often limited. Whereas many patients receiving assistance directly from the manufacturer apply once and are covered for life, foundation-
Based assistance is generally time-limited. One physician told his patient, “They help you for a certain amount of time. And then you're cut off. Because they only, then you have to, you know, reapply for the following years. So, it’s year to year. But I've never really seen it last for a whole year. Maybe six months, eight months and then you're without.” Whether every six months, or annually, these patients have to submit applications to extend their copay support. Increasing the frequency of these applications also increases the time and energy patients need to devote to obtaining assistance, and the likelihood that their assistance will not get renewed.

Furthermore, the pool of funds available for foundations can dry up, and patients can lose their support: “A lot of times you find with these foundations that the [manufacturers] give money to the foundation, and at some point, those funds aren’t unlimited…sometimes they expire, sometimes eligibility changes” (Personal Interview, Michael DeCoske). The burden associated with having to deal with a separate company, then, is compounded both by the frequency with which that interaction has to happen and the uncertainty surrounding the continuity of funds.

**Discussion**

Analysis of 268 transcripts with cost conversations shows that high cost can have broad effects on a patient’s life, including but not limited to health outcomes. Specifically, whether anticipated or unexpected, high cost can cause emotional distress, difficulty dealing with the complexity of cost-reducing strategies, and cost-induced non-adherence to treatment regimens. Previous analysis shows that applying for copay assistance and switching to less costly alternative treatments are two common cost-
reducing strategies (Hunter, Zhang et al. 2015). Identifying these strategies can help inform where to focus future policy efforts aimed at relieving the burden of high cost.

This section presents policy options that relate to these two strategies and offers recommendations for moving forward. The process for arriving at these policy options followed a progression from the clinic transcripts to the cost reducing strategies presented in Hunter, Zhang et al. (2015), to policy recommendations. Thus, the first part examines OOP cost cap legislation, which is one way to categorically reduce patient OOP liabilities. The second section examines possibilities for making it easier to get copay assistance when on public health insurance.

**Legislation to Cap Out-of-Pocket Costs**

Patients undoubtedly suffer from the out-of-pocket costs associated with prescription medications, particularly specialty drugs. The high cost of these treatments is compounded by the long time horizon associated with chronic conditions like RA (Personal Interview, Desai). Therefore, capping the out-of-pocket cost burden for patients could help alleviate some of the problems associated with high-cost treatments, and help patients avoid the need to switch to less effective treatment regimens. As demonstrated above, the impacts of high cost are broad.

Among people prescribed expensive drugs, these caps can be the only protection against unmanageable costs (See Table 5). Take Jane, for example, whose benefits changed such that her Enbrel payment increased nineteen fold. Were her payments capped at $250, the increase would have been at most $170, or about 200%; still a steep rate hike, but much more manageable than $1,600. Another woman “used to take Humira, and, um, stopped it about a year ago” because her OOP costs rose from “$35 for
patients routinely have to stop taking beneficial medications when the costs become too burdensome. Unfortunately, the transcript cannot tell us the maximum she could have afforded, but $250 can only have been closer to her ability to pay.

Patients with such high costs also benefit from the way the cap defrays patient liability across the year. One patient complained to her doctor, “Our deductible's $4,000 a year and we've hit it already. I just cannot keep throwing money at the health system.” Most United States households with incomes below 400% of the Federal Poverty Level (roughly $100,000 in 2015 for a family of four) have less than $3,000 cash on hand (Pollitz, Cox et al. 2014). If, for example, Jane lived in one of these families, she would have to lay out over half her liquid assets in January, and continue to do so each month until she hit her annual OOP limit. With a cap, however, the patient responsibility is spread out across the year. This effect can be tremendously helpful for patients living on limited or fixed income.

To reduce the OOP cost burden among patients using expensive medications, seven states have implemented out-of-pocket drug cost caps. Six of these states use monthly caps ranging from $100 to $500, and one has an annual limit of $3,500 per drug (Figure 1). New York decided to exclude the use of specialty tiering, which ipso facto imposes an OOP cap because lower formulary tiers use lower levels of cost sharing.

Prescription drug caps have gained less momentum on the national stage, however, until recently. Democratic presidential candidate Hillary Rodham Clinton announced in September 2015 a plan to limit prescription drug out-of-pocket costs to $250 per prescription per month (Becker 2015). Even though the Affordable Care Act caps annual
OOP spending for individual market plans at $6,600 for individuals and $13,200 for families, some patients on expensive medications hit those caps in their first month of coverage. These monthly caps would help patients defray the costs of care over the course of the year (Dickson 2015).

**Recommendation**

System-wide cost shifting would result from broad monthly OOP caps. The insurance industry would absorb some of the costs, patients would assume part through higher premiums, manufacturers would continue to offer patient assistance, pharmacies would likely be reimbursed less for the same products and government would pay for part through subsidies. The American society needs to critically examine its comfort level with the collective helping the individual foot the bill. It is reasonable that patients taking expensive – and also extremely effective – drugs over a long time horizon receive support in covering treatment costs.

However, unilateral out-of-pocket cost caps may be too blunt of an instrument. That is, they would impact more people than the problem affects (Personal Interview, Desai). Patients with generous copay assistance programs or low cost sharing liabilities will not derive any benefit from these caps; instead only experiencing the likely harms (e.g., higher premiums, more restrictive Utilization Management requirements, etc.). Thus, the caps should only be applied to beneficiaries of public health insurance programs. Because these people have a harder time receiving copay assistance, they would stand to gain more than patients with commercial insurance. Although payers who operate in both the commercial and public markets would likely increase rates and cost sharing in their commercial plans to offset the limitations in public plans, defraying the
costs across society is arguably desirable; in this case, costs shift away from the elderly and the poor.

**Copay Assistance**

In the wake of cost sharing increases for prescription medications, drug companies try to dampen the excess burden on patients through implementing patient assistance programs. Manufacturers use these programs – also commonly called copay coupons, copay assistance programs and prescription drug discount cards – to reimburse patients buying brand name drugs so their OOP liability more closely resembles that of a generic drug. The popularity of these programs has exploded in recent years (Personal Interview, Desai). In 2014, 561 coupon programs covered more than 700 different brand-name medications, representing a 34% increase over the previous two years (Starner, Alexander et al. 2014). In 2010, roughly one hundred million prescriptions involved coupons (Ross and Kesselheim 2013).

**Recommendation**

The public and private sectors can both work to reduce patient struggles with copay assistance. In the public sphere, new legislation could allow manufacturers to provide copay assistance directly to Federal health insurance beneficiaries without worrying about anti-kickback or fraud-and-abuse violations. This solution would streamline the process for patients obtaining assistance and create parity between different PAPs that cover the same drugs. There are two important concerns, however. First, manufacturers could effectively induce utilization, leading to the problems these laws are meant to prevent. The challenge is to protect the market forces while minimizing the distress and harm imposed on patients. Second, lower cost barriers would increase utilization for
specialty drugs within the Medicare and Medicaid populations, thereby greatly increasing the drug spend in these federal programs (Personal Interview, Desai). To make this change without derailing the federal health budget would require finding a sufficiently large offset to make up for the new expenditures. To date, this discussion has been sparse and little pursued.

A less radical step would involve regulating the nature of copay assistance given out through independent charities. Because many of the problems stem from frequent application cycles, eligibility requirements and little guarantee that the money will continue to flow, the Federal government could regulate eligibility requirements and impose minimum time limits on assistance – perhaps one year, or even two or five – thus creating a de facto guarantee for the period of assistance. To pursue this option, legislators would need financial analyses of the funding resources available to charities.

A third option involves regulating the frequency and magnitude of cost sharing increases from commercial insurers. In much the same way insurers can only impose premium rate increases to certain levels could also protect patients within a certain band, limiting coinsurance and copay increases to certain levels could also protect patients who remain unable to receive copay assistance from significant increases in OOP responsibility year-over-year.

Lastly, the Internal Revenue Service could use tax offsets for individuals with high out-of-pocket expenses. That is, retrospective analyses could determine the OOP costs a patient faced over the past year and rebate a portion of the money above a certain threshold (e.g. a percentage of income). This last option would serve as a stop-gap measure; for those patients who are on public insurance, cannot get copay assistance
through a third-party charity organization, or whose insurance company continues to use high cost sharing, the rebates would help protect against the damaging effects of high cost.

Given these four public options, the government should pursue foundation and cost sharing increase regulations. These rules should provide a minimum level of assistance available through third party foundations for patients who are not able to get help directly from manufacturers. Furthermore, insurers should not be allowed to indiscriminately increase cost sharing year-over-year.

In concert with government intervention, an opportunity also exists for the private sector to help mitigate the burden associated with enrolling in copay assistance programs. As a non-profit academic medical center, Duke University Hospital invests in patient assistance resources. In addition to utilizing pharmacists for clinical advice and support, “[Duke is] going to actually put a pharmacy technician in the clinic… [to] help with prior authorizations and also with connecting patients to resources that exist” (Personal Interview, Michael DeCoske). These pharmacists, acting together with larger teams, will advocate on behalf of patients and help them navigate application processes. “[Duke looks at] any time a patient has a copay over $100, we’re thinking what are resources that are available…. For anybody over $100, we’re automatically assessing is there anything that this person can be eligible for” (Personal Interview, Michael DeCoske). Certainly great pharmacy resources are available to patients at Duke; however, a short distance in any direction and it is easy to find patients for whom those services are not available.

To be sure, despite its immense benefits to patients, this type of service is not widespread. Staying up to date with various manufacturers’ PAPs is not easy, and
staffing people equipped to walk patients through their options can be time consuming. Thus, some providers do not see the benefit of such robust financial counseling to their bottom line, and others simply do not have the funds to provide it. Other times businesses face conflicts of interest. For example, payers often discourage patient assistance programs because they decrease patient liability and increase utilization, thereby increasing claims.

Despite competing business interests, it is important to remember that diminishing the cost barrier can improve medication adherence and reduce patient distress; thus it is reasonable to assume that a few dollars spent today on patient support services could save money in downstream costs (Mojtabai and Olfson 2003). And, importantly, these types of programs would help both federal health insurance beneficiaries and patients with commercial insurance. As a greater number of patients take increasingly expensive drugs, providers should invest in programs that connect patients with PAPs. To encourage these programs, the government should provide incentive payments to providers in much the same way they incent adoption of electronic health records and other programs that help patients better interact with the healthcare system.

**Connecting the Policy Recommendations and Patient Experience Themes**

One can reasonably assume that these policy recommendations would help address the issues represented by the patient experience themes. For example, high cost sometimes causes patients to suffer emotionally, financially and physically. Moreover, this suffering can manifest in emotional responses and cost-induced non-adherence (Themes 1 and 3). Monthly prescription OOP cost caps could thus help reduce suffering by limiting the financial burden associated with prescription medications. In addition, my
findings suggest that complexity can stand in the way of successful cost reducing strategies (Theme 2). Thus, making copay assistance applications more straightforward for Medicare and Medicaid beneficiaries – and mandating that the duration of the aid last longer – would minimize complexity and help physicians and patients use this strategy more effectively to reduce cost.

**Conclusions**

The cost burden associated with healthcare in the United States is growing and significant. Because much discussion has been devoted in recent years to decreasing the uninsured population, it is easy to forget that even those with insurance can face substantial out-of-pocket costs. This problem rings especially true for patients with chronic conditions like Rheumatoid Arthritis, care for which generally involves expensive specialty medications and treatments over a long time horizon.

Health insurance can successfully insulate patients against high cost, but in some cases the cost-sharing mechanisms insurers use to defray their expenses and combat moral hazard expose patients to burdensome medical bills. For example, Rheumatoid Arthritis patients prescribed highly effective specialty pharmacy products subject to high cost sharing (e.g., coinsurances) are at an elevated risk for experiencing high cost. These patients are thus caught in a tough situation trying to juggle the tradeoffs between highly effective medications and significant costs.

Previous research shows that physician-patient communication around costs of care can facilitate more cost-effective and preference-sensitive treatment decisions. This study examined the patient experience in the face of high cost, the ways doctors and patients discuss costs and health policies that could facilitate cost reduction.
An investigation into 268 cost conversations between rheumatologists and rheumatoid arthritis patients revealed that high cost poses a salient harm and dilemma to rheumatoid arthritis patients. They often look to their doctor for help mitigating costs, and while physicians do have a number of cost-reducing strategies at their disposal, they are better able to use them when they can talk with patients about specific cost problems and life circumstances.

This thesis was framed around three main questions: (1) In rheumatology clinic encounters, how often do patients and physicians discuss issues of high cost? (2) What elements of the patient experience emerge during clinical interactions about high cost? (3) What are potential policy solutions to help relieve high cost for RA patients? With respect to the first question, 23.6% \((n = 155)\) of clinic encounters between rheumatologists and rheumatoid arthritis patients in this sample dealt with issues of high cost. To answer the second question, three themes emerged – emotional responses, difficulty in the face of complexity, and cost-induced non-adherence. Finally, in response to the third question, more streamlined and accessible copay assistance programs, and monthly prescription OOP cost caps for Medicare and Medicaid beneficiaries are policies that would help mitigate issues of high patient cost while minimizing ripple effects through the greater health system.

Although rheumatoid arthritis care is not limited to pharmaceutical therapy, the vast majority of high cost conversations in this sample centered on the costs associated with drug spending. Thus, this study identified more easily accessible copay assistance and out-of-pocket spending caps as two salient policies that could help reduce patient cost burdens. With respect to copay assistance, problems may arise when patients are
covered under public health insurance (e.g. Medicare, Medicaid, etc.) because they cannot get assistance directly from the manufacturer. Seeking copay assistance through third-party foundations creates an extra hurdle for patients who need subsidies to afford their medications. In the face of these cost-problem triggers, some states (and national political leaders) are proposing and implementing monthly out-of-pocket caps. These limits – ranging from $100-500 – can help insulate patients against the high costs associated with RA therapies. As indicated above, lower costs lead to better adherence, less overall hardship, and myriad other positive outcomes.

My findings fit well within the context of previous research done on cost conversations and out-of-pocket burdens. United States healthcare spending is on the rise, driven in part by pharmaceutical costs. The beginning of the twentieth century bore witness to a host of new breakthrough medicines in the RA space. These biologic DMARDs can be exceptionally effective at relieving symptoms, slowing disease progression and improving quality of life. That said, they are also significantly more expensive than non-biologic medicines. To accommodate these costs, payers use copays, coinsurances and deductibles to push treatment costs onto patients.

Although this project provided an opportunity to study real conversations between rheumatologists and RA patients, it is limited in important ways. First, the transcripts in this sample are non-representative of the RA population at large. Verilogue does work to recruit physicians from across the country, but transcripts are limited to those practices whose physicians opt into the program. Furthermore, Dr. Ubel and his team previously sifted through the 656 RA transcripts obtained from Verilogue based on predefined criteria to arrive at the condensed set of 268 cost conversations used in this thesis. A
more representative sample of transcripts would allow for statistically valid statements about the cost problems doctors and patients face in clinical settings. Second, this study provides very limited quantitative analysis. Because the investigation was concerned more with exploring the patient experience in the face of cost problems, and relevant health policies, than it was with quantifying the frequency of each cost problem, the results section does not report which problems surface most often. Third, the transcripts only show one point in time. In other words, I was unable to see the trajectory of a patient’s care over time. It is possible, then, that the doctor and patient discussed high cost, a particular cost-reducing strategy, or a cost-problem trigger in previous or future clinic visits. My analysis was limited to the discussions found in discreet encounters. Lastly, my recommendations do not include non-policy solutions such as medical education. Providers often say they lack the training and preparation to have cost conversations with their patients. Including cost conversation preparation in medical school or residency program curricula could help providers better engage their patients around issues of high cost.

The solution to these problems of high cost must span the entire healthcare system. Most readily apparent is the need to lower the costs of prescription drugs. The current path is not sustainable, and drug manufacturers have a role to play in absorbing some of the lost profits. After all, they have realized among the highest profits in the US economy for some time (Personal Interview, Zafar). Opportunity for change exist in the regulatory space as well. For example, the Centers for Medicare and Medicaid Services is not allowed to negotiate drug prices with manufacturers; repealing this provision of the Medicare Modernization Act could help drive down prescription drug spending.
Similarly, payers can and should use tactics like Value Based Insurance Design (VBID) – a system in which they pay for drugs that work well, and don’t pay for ones that are ineffective – to signal to manufacturers that unbridled reimbursement cannot continue. Moreover, systems like VBID benefit patients because they shield them from cost sharing when using these effective products. Lastly, physicians and patients need to be involved. “When doctors are vocal, they get heard,” and can thus use their lobbying power to effect change around drug pricing and access (Personal Interview, Zafar). Providers also have a responsibility to talk with their patients and prescribe drugs that are high value, avoiding high cost when possible. That conversation, by necessity, involves the patients, who need to learn to be more comfortable raising concerns with doctors, and try to be more educated about their own healthcare needs.

The American healthcare system is in the midst of a sea change. Driving the tumult, in part, is the country’s attempt to grapple with two fundamental questions: to what degree will we help patients access care, and to what degree are we comfortable watching them go without? At the end of the day, the consequences of high cost sit most solidly in the laps of patients: those who can’t fill prescriptions or have to foreclose on homes or live in constant, curable pain. For them, high cost is not a puzzle to be solved, but an immediate stressor and barrier to a better quality of life. It can leave them feeling confused, worried and helpless. As policymakers, we have a great opportunity to create smoother pathways and lower barriers to care. Not to make care free, but to use cost sharing as intended instead of allowing it to create a financially toxic environment.
Appendix A

**Interviewee:** S. Yousuf Zafar, MD, MHS  
**Title:** Medical Oncologist, Duke Cancer Center  
**Interview Time and Location:** October 20, 2015 – 1:00pm – Hock Pavilion, 6th floor

**Background**  
- How/When did you get interested in the cost burden of healthcare?  
- When you see evidence of cost-induced non-adherence here at Duke,  
  - What does that look like?  
  - Is there data on why this happens? Who it happens to? Are there predictive analytics for anticipating when someone may become non-adherent due to costs?

**Copay Assistance**  
- In your experience, is copay assistance an effective cost-reducing strategy for physicians and patients?  
  - Are there other ways of mitigating OOP cost that you see as equally, or more, effective?  
- Are there services in place to help people get copay assistance (e.g. counselors, hotlines, pamphlets, physician training, etc.)?  
  - Especially within Medicare/Medicaid population. Do you see these people disproportionately struggling?  
- As someone who is also involved in more broad conversations about health policy and cost containment, how do you think the individual benefits of copay assistance stack up against the effects they have on overall health system spending? That is, do the benefits to patients outweigh the effects of driving up total drug spend?

**OOP Caps**  
- There are a lot of stakeholders involved with this cost cap decision. Patients and manufacturers generally like it, payers generally don’t. How do you see this issue playing out over the coming year or two?  
- Similar to the copay assistance, do you think the benefit of capping the costs will outweigh the other consequences (e.g. higher premiums, perhaps more strict UM requirements, etc.)?

**Miscellaneous**  
- I have been giving a definition of financial toxicity in my paper, but it would be great to have one quoted from you.  
- Drawing on your depth of clinical and policy experience, what public and private sector solutions do you see for this issue of patients facing high cost?  
- Given that the primary focus over the past five years, post-ACA, has been on reducing the uninsured, do you think we will start moving toward a more national discussion of issues like cost burden, even among the insured population?
Interviewee: Rujul Desai  
Title: Vice President, Avalere Health  
Interview Date, Time and Location: October 15, 2015 – 3:30pm – Phone

Copay Assistance

- In your experience, is copay assistance an effective cost-reducing strategy for doctors and patients?
  - Are there other ways of mitigating OOP cost that you see as equally, or more, effective?
- Are there broadly services in place to help people get copay assistance (e.g. counselors, hotlines, pamphlets, physician training, etc.)?
  - Especially within Medicare/Medicaid population. Do you see these people disproportionately struggling?
  - Is this as true at large PBMs?

Medicare Part B / Part D Inconsistency

- Fundamentally, what is the problem here?
  - Access?
    - Cost
    - Convenience
- Is there a way for doctors to most effectively prescribe drugs through Part B or Part D, based on the patient?
- Would consolidating the two programs – or at least getting rid of their inconsistencies – be a good thing or a bad thing, from your perspective?
- In your opinion, is there a way to allow manufacturers to give assistance to Medicare/Medicaid benes without having fraud and abuse concerns?
- If none of above, what can be done about this?

OOP Caps

- There are a lot of stakeholders involved with this cost cap decision. Patients and manufacturers generally like it, payers generally don’t. What do you see as pros and cons? And who do you think will ultimately win?
- If this does happen, what will change for how your pharma clients do business?
Interviewee: Kyle Cavanaugh
Title: Executive Vice President, Administration, Duke University
Interview Time and Location: 9:30am, Room 204A-705 Broad Building

Background
- Because Duke self-insures, do they do things differently than an independent insurer would?
  - Especially with regard to cost sharing, etc.?
- Do you see evidence of cost-induced non-adherence here at Duke?
  - What does that look like?
  - Do you have data on why this happens? Who it happens to? Are there predictive analytics for anticipating when someone may become non-adherent due to costs?
- There’s an interesting dynamic here at Duke, because you effectively operate both the payer and provider ends of the deal? Is it a little bit like the right hand giving money to the left hand? And how does that affect decisions about utilization incentives?

Copay Assistance
- As a plan that covers over 60,000 lives, do you actively encourage the use of Patient Assistance programs (e.g. copay assistance)?
  - Are there services in place to help people get copay assistance (e.g. counselors, hotlines, pamphlets, physician training, etc.)?
- How does the use of copay assistance affect your bottom line?

OOP Caps
- There are a lot of stakeholders involved with this cost cap decision. Patients and manufacturers generally like it, payers generally don’t. Has duke taken a public stand on this issue? Is it waiting to see if North Carolina takes any steps in that direction?
- Let’s say there was a national cap set at $250 per Rx per month. Are there benefit designs at Duke that would have to change for patients to come in under the cap?
- If this does happen, what will change for how you do business? In other words, how will the Duke health plan make up for the money it would lose from reducing patient liability?
Interviewee: Dr. Michael DeCoske, PharmD, BCPS
Title: Associate Chief Pharmacy Officer, Ambulatory Services, Duke University Hospital
Interview Time and Location: 3:00pm, Von Der Heyden Pavilion

Background
- What do you do?
- How does ambulatory pharmacy differ from other divisions within the pharmacy space?
- Do you see evidence of cost-induced non-adherence here at Duke?
  - What does that look like?
  - Do you have data on why this happens? Who it happens to? Are there predictive analytics for anticipating when someone may become non-adherent due to costs?

Copay Assistance
- In your experience, is copay assistance an effective cost-reducing strategy for rheumatologists and patients?
  - Are there other ways of mitigating OOP cost that you see as equally, or more, effective?
- Are there services in place to help people get copay assistance (e.g. counselors, hotlines, pamphlets, physician training, etc.)?
  - Especially within Medicare/Medicaid population. Do you see these people disproportionately struggling?
- Because Duke has a self-insured population, does copay assistance affect the bottom line?

Medicare Part B / Part D Inconsistency
- Is there a way for doctors to most effectively prescribe drugs through Part B or Part D, based on the patient?
- Would consolidating the two programs – or at least getting rid of their inconsistencies – be a good thing or a bad thing, from your perspective?

OOP Caps
- There are a lot of stakeholders involved with this cost cap decision. Patients and manufacturers generally like it, payers generally don’t. As an academic medical center, is there any preference?
- If this does happen, what will change for how you do business?

Miscellaneous
- I read online that Duke opened a specialty pharmacy in the cancer center, originally intended for oncology and transplant medicines. Has that expanded to other conditions?
  - What are the benefits to Duke to expanding specialty pharmacy capabilities?
  - What are benefits to patients?
Are Duke rheumatologists encouraged to begin with less-expensive medications and work their way up to the more expensive biologic DMARDs? In other words, is there an “approved” step therapy in the RA space?
References


National Center for Health Statistics (2014). "Special Feature on Prescription Drugs."


